EXHIBIT C

-Translation-

Executed Copy

33 O 158/09

Regional Court of Cologne
Court Order

In the matter of

Arizant Deutschland GmbH, legally represented by its Managing Director Robert Gerhard Buehler, Gary Maharaj, Technologiepark 24, 22946 Trittau,

Applicant,

Attorneys at law: Attorneys at law Reimann, Osterrieth, Köhler, Haft, Steinstraße 20, 40212 Düsseldorf

versus

1. Augustine Biomedical + Design, 6581 City West Parkway, legally represented by Dr. Scott D. Augustine, Eden Prairie, 55344 Minnesota, United States
2. Hot Dog International, 6581 City West Parkway, legally represented by Dr. Scott D. Augustine, Eden Prairie 55344 Minnesota, United States,
3. P.J. Dahlhausen & Co. GmbH, legally represented by its Managing Directors Peter-J. Dahlhausen, H.W. Deutsch, Emil-Hoffmann-Str. 53, 50996 Cologne,

Respondents,

the applicant has shown credibly the requirements for the following preliminary injunction are fulfilled by providing promotional material of the respondents as well as further documents.

Upon request of the applicant the following is ordered, due to the urgency without oral hearing:

1. The respondents are ordered, upon payment of an administrative fine to be determined by the court up to € 250,000.00 for each case of non-compliance - alternatively administrative imprisonment - or administrative imprisonment of up to six months to refrain from advertising

   in the Federal Republic of Germany with the following statements:

a) "Recent studies have shown the contamination of the Bair Huggers blowing units with bacteria. These units blow in the hour many million bacteria-sized particles into the operation room. No wonder that the U.S. Department of Public Health called the Bair Hugger units reservoirs of infection."

b) "In the journal "Infection Control and Hospital Epidemiology" the inside of a Bair Hugger unit was described as the source of infection with multi drug resistant Acinetobacter. Regardless of this report a manufacturer does not offer a protocol for cleaning the insides of Bair Hugger blowers and hoses."

c) "Particle counters have measured more than 50 million germ-sized particles per hour blowing from Bair Hugger units into the operating theatre."

d) "Can hot air hoses be cleaned? NO! Routine wiping does not remove contaminants from the valleys of the hose. The 180 creases of the 2 meter hose are nearly impossible to clean."

if this is undertaken as follows:

2. The respondents bear the costs of the proceedings as joint and several debtors.

Reasons:

The action for a preliminary injunction is admissible and founded.

The reason for an injunction is assumed according to sec. 12 para. 2 UWG.

The claim for an injunction originates from sec. 3, 4 no. 7, 5, 8 UWG.

The applicant is according to sec. 8 UWG entitled to injunctive relief, because the objected behaviour is an act of unfair competition pursuant to sec. 3 UWG.

The applicant has demonstrated and shown credibly that the advertising messages stated in the operative provision of the judgement are delusive and degrade the goods "Bair Hugger" marketed by the applicants according to sec. 4 no. 7, 5 UWG.

The decision regarding the costs is based on sec. 91 ZPO.

Value in dispute: € 50,000.00

Cologne, 2 June 2009
33. civil chamber

Dr. Schwitanski Ingendae Chang-Herrmann

Executed

[Signature]

Schlürscheid, Justizhauptsekretärin
as the clerk of the court

EXHIBIT D

Translation

COLOGNE REGIONAL COURT

IN THE NAME OF THE PEOPLE

JUDGMENT

Date of Pronouncement: February 15, 2011
Fietkau, Court clerk
as Registrar of the Court

-3 3 O 256/09-

In the legal dispute

of Arizant Deutschland GmbH, Technologiepark 24, 22946 Trittau, represented by its managing directors Robert Gerhard Buehler, Gary Maharaj, at the same address

Plaintiff,

Counsel: Attorneys at Law Reimann Osterrieth Köhler Haft, Steinstraße 20, 40212 Düsseldorf

versus

Augustine Biomedical + Design, 6581 City West Parkway, Eden Prairie Minnesota 55344, USA, represented by Dr. Scott D. Augustine, at the same address,

Defendant 1) and Counterplaintiff 1)

Hot Dog International, 6581 City West Parkway, Eden Prairie Minnesota 55344, USA, represented by Dr. Scott D. Augustine, at the same address,

Defendant 2) and Counterplaintiff 2)

Counsel for defendant 1) and 2) Rechtsanwälte Arqis, Prinzregentenstraße 48, 80538 München

P.J. Dahlhausen & Co. GmbH, Emil-Hoffmann-Straße 53, 50996 Köln, represented by its managing directors Peter-J. Dahlhausen, H.W. Deutsch, at the same address,

Defendant 3),

Counsel for defendant 3): Rechtsanwälte Dr. Bartmann, Retsch und Kollegen, Hauptstraße 1-7, 50226 Frechen

the 33rd Civil Division of the Cologne Regional Court, following the oral hearing on December 21, 2010 before Presiding Judge at the Regional Court Dr. Schwitanski, Judge at the Regional Court Wuttke and Judge at the Regional Court Chang-Herrmann,

have passed the following judgement:

I. The defendants are ordered to refrain from advertising with the following statements:

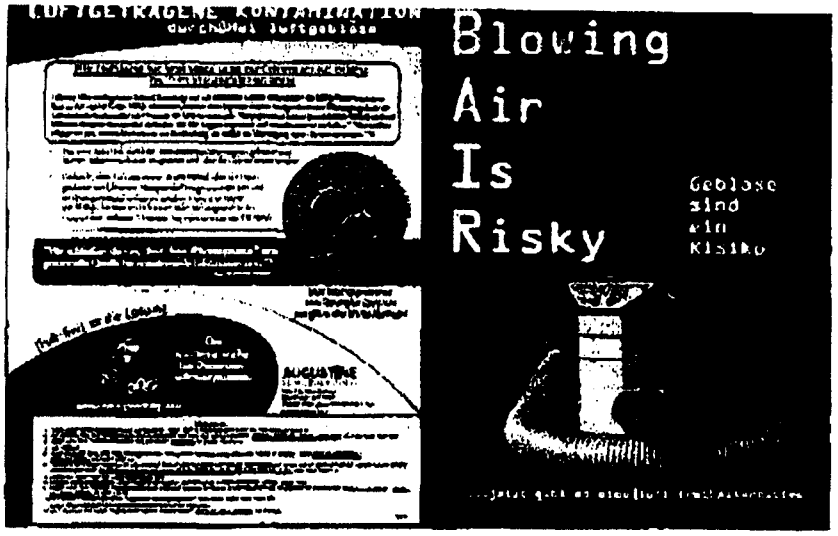
a) "Recent studies were frequently able to detect contamination of the Bair Hugger®1 blowers with bacteria. These devices blow many million bacteria-sized particles into the operating room every hour. It is hardly surprising that the U.S. Department of Public Health referred to the Bair Huggers as reservoir of infections."

b) "The Infection Control and Hospital Epidemiology" journal described the interior of a Bair Hugger device as a source of infection with acinetobacter which are resistant against several medicaments." Despite these reports the manufacturer does not offer a procedure with which to clean the inner side of the Bair hugger blower or hoses."

c) "With particle counters it was found that more than 50 million bacteria-sized particles are blown into the operating room from the Bair Hugger devices."

d) "Is it possible to clean hot air hoses? NO! During routine cleaning the contaminations are not removed from the recesses of the hose. It is practically impossible to remove contaminations from the recesses in the 180 windings of a two meter hose."

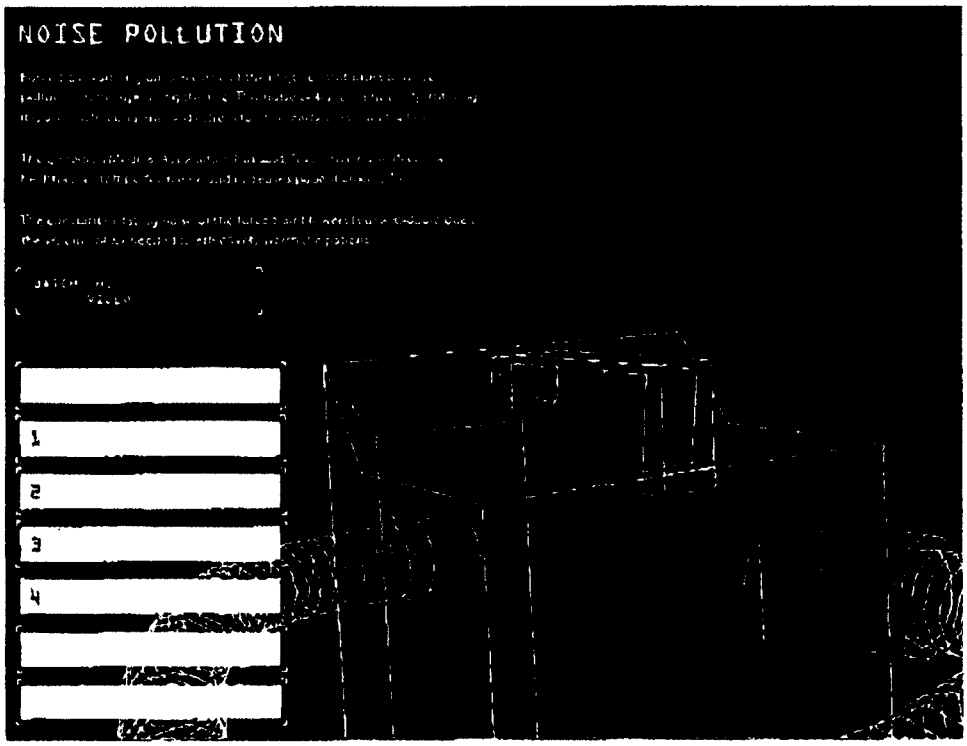
if this is done in the following manner:


Blowing
Air
Is
Risky


"INFEKTIONSRESERVOIRE"

e) „Forced-air warming units are one of the major contributors to noise pollution in the operating theatre. This noise pollution is not only irritation, it is also distracting and adds stress to the already stressful situation. The Canadian Medical Association has said, „excessive noise decreases health-care staff performance and increases patient anxiety." The constant irritation noise of the forced-air blowers is unavoidable due to the volume of air needed to effectively warm the patient."

if this is done in the following manner:


NOISE POLLUTION
1
2
3
4

II. For each case of non-compliance the defendant faces determination of an administrative fine of up to 250,000 EUR, or administrative detention, or administrative detention of up to six months.

III. The defendants are ordered to provide information to the plaintiff regarding the scope within which they have disseminated the advertisements referred to in no. I, specifying the dissemination period, advertising media, circulation figures and area of coverage.

IV. It is established that the defendants are obliged to indemnify the plaintiff for all losses that have been incurred or will be incurred from the actions listed under I.

V. On the remaining counts, action and counteraction are dismissed.

VI. Plaintiff and defendants 1) - 3) bear 50% of the court costs and out-of-court costs, and defendant 1) and 2) bear the other 50%. Beyond that, there is no reimbursement of costs.

VII. The judgment is provisionally enforceable against provision of a security of € 60,000.

FACTS OF THE CASE

The parties compete in the field of patient warming systems. The managing director of defendant 1) and 2) was the founder of the US parent company of the plaintiff and inventor of the plaintiff's patient warming system sold under the name "Bair Hugger".

Defendants 1) and 2) produce patient warming systems sold by defendant 3) under the name "Hot Dog" in Germany, and by defendant 1) and 2) in the USA, among other countries.

Defendant 3) operates the German internet page www.dahlhausen.de . From there, there used to be a link to the internet page www.hotdogwarming.com (page 48 of the court files).

On the English-language web page www.hotdogwarming.com of defendant 2), information can be found about defendant 3) in the "contact us" section when using the "dealer search" function (page 8 of the court files).

Defendant 1) operates the English-language web site www.augbiomed.com . Users with an interest in Hot Dog patient warming systems visiting this page were also led to the web site of defendant 2) (page 36 of the court files). It was possible to download various brochures from the "Resources" section on this page. These included the brochure "The next wave" which could also be downloaded in German (page 9 of the court files). It is meanwhile also undisputed that the brochure "Blowing air is risky" was made publicly accessible at least between October 2008 and May 2998 via the web site www.hotdogwarming.com, as well as the other German-language brochure. Both brochures have the logos of defendant 1) and 2) printed on them (page 37 and 50 of the court files).

There was moreover a link to the English page www.blowingairisrisky.com on the internet page www.hotdogwarming.com. Apart from various statements about patient warming and forced air warming systems, the internet page www.blowingairisrisky.com also contained the logo of defendant 2) and a call upon users to visit the website of defendant 2).

The plaintiff advertises its system on the internet at www.arizant.com and through advertising brochures. For further details of the advertising statements made by the plaintiff concerning its "Bair Hugger" products, we refer to the internet printouts submitted as Exhibits B10 - B13 (pages 419 - 422 of the court files) and the brochures.

The plaintiff alleges that the German-language brochure "Blowing air is risky" of defendant 1) and 2) was distributed in the Werner-Wicker Clinic in Germany, i.e. on the German market, and was the subject matter of sales talks conducted by a field staff member of defendant 3). It considers the statements about its "Bair Hugger" patient warming systems made by the defendants in their brochure "Blowing air is risky" and on the internet page www.blowingairisrisky to be unfair, because they are misleading and generally disparaging. In contrast to that, it considers its own advertising statements to be correct and in conformity with competition law.

The plaintiff requests as held.

It additionally requests

that the defendants be ordered to bear the costs of a publication of the judgment in "Der Anästhesist", "Die Schwester, der Pfleger" and "A&I Anästhesiologie und Intensivmedizin".

The defendants request

that the action be dismissed.

By way of counterclaim, defendant 1) and 2) request that

the plaintiff be ordered, upon pain of an administrative fine to be determined by the Court of up to EUR 250,000.00, for each case of non-compliance - alternatively administrative detention - or administrative detention of up to 6 months, to refrain from using the following statements for advertising purposes either literally or correspondingly:

1. "The Bair Hugger model 505 provides safe and quiet patient warming worldwide", if this is done in the following manner:

Bair Hugger™ Therapie

Temperaturmanagementgeräte und Zubehör

Temperaturmanagement-Geräte - Modell 505

Bair Hugger - Temperaturmanagementgeräte sind die Standardversorgung in der Umluft-Wärmetherapie. Das Bair Hugger Modell 505 liefert weltweit eine sichere gerätschonende und wirksame Patientenerwärmung.

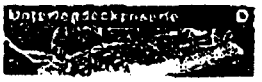
- Die geringen Abmessungen beeinträchtigen Ihren Arbeitsplatz nur minimal
- Das leichte Gewicht macht den Transport und den Aufbau zu einem Kinderspiel
- Freistehend oder einfach an einer Infusionsstange, einem Bettgestell oder auf einem optionalen Rollwagen befestigt
- Mit dem eingebauten Betriebsstundenzähler ist die empfohlene Wartung einfach zu planen
- Der Schlauch mit Schnappverschluss ist deutlich schmutzabweisender, um einen leichten Anschluss und die Positionierung der Decke zu gewährleisten

PRODUKTSPEZIFIKATIONEN

Produktinformation

Ressourcen

Kundendienst



Arizant

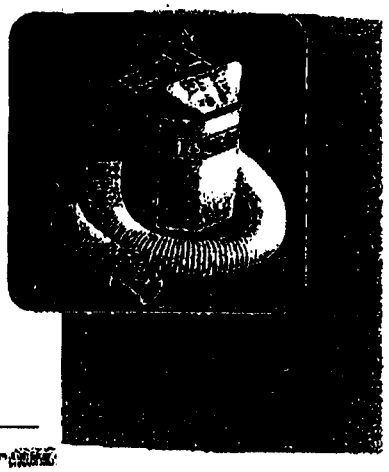
Temperaturmanagementgeräte

Modell 505

Temperaturmanagementgerät

Mit dem hervorragenden Leistungsstandard der Lieblau-Temperaturmanagementsysteme liefern das Bair Hugger Modell 505 [illegible] und wirksame [illegible]

- Die geringen Abmessungen beeinträchtigen Ihren Arbeitsplatz nur minimal.
- Das leichte Gewicht machen den Transport und den Aufbau zu einem Kinderspiel.
- Freistehend oder einfach an einer Infusionsstange, einem Bettgestell oder auf einem speziellen Rollwagen befestigt.
- Mit dem eingebauten Betriebsstundenzähler ist die empfohlene Wartung einfach zu planen.
- Der Schlauch mit Schnappverschluss ist dreifach schwenkbar, was einen leichten Anschluss und die Positionierung der Decke zu gewährleisten.
- Die Kompatibilität mit dem 241° Blut und Flüssigkeits-Wärmer liefert zwei Wärmetherapien in einem Gerät.



Technische Daten

Abmessungen
33 H x 75 B x 28 cm T

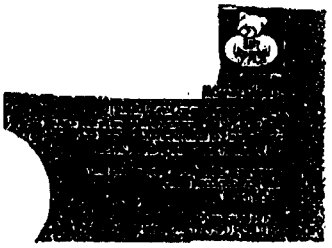
Gewicht
6,2 kg

Betriebstemperaturen
Hoch: 43 ± 3°C
Mittel: 38 ± 3°C
Niedrig: 32 ± 3°C

Leckstrom
Entspricht den gesetzlichen Leckstrom-Vorschriften.

Filter
[illegible]

Gerätleistung
110-120 V~, 60 Hz, 11,5 A
220-240 V~, 50 Hz, 4,5 A
100 V~, 50/60 Hz, 11,5 A



Arizant
Healthcare

[illegible]

2. "Each temperature management device is tested individually in order to ensure safe operation."
3. "Highly efficient 0.2 µm air filter."

if this is done in the following manner:

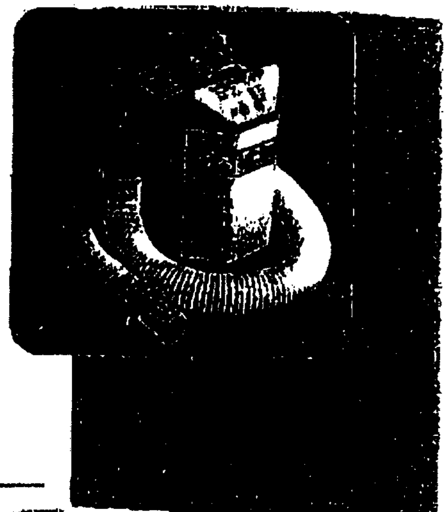
Temperaturmanagementgeräte

Modell 505

Temperaturmanagementgerät

Mit dem hervorragenden Leistungsstandard der Gebläseluft-Temperaturmanagementgeräte liefert das Bair Hugger Modell 505 [illegible] und wirksame [illegible]

- Die geringen Abmessungen beeinträchtigen Ihren Arbeitsplatz nur minimal.
- Das leichte Gewicht machen den Transport und den Aufbau zu einem Kinderspiel.
- Freistehend oder einfach an einer Infusionsstange, einem Bettgestell oder auf einem optionalen Rollwagen befestigt.
- Mit dem eingebauten Betriebsstundenzähler ist die empfohlene Wartung einfach zu planen.
- Der Schlauch mit Schnappverschluss ist dreifach schwenkbar, um einen leichten Anschluss und die Positionierung der Decke zu gewährleisten.
- Die Kompatibilität mit dem 241® Blut- und Flüssigkeits-Wärmer liefert zwei Wärmetherapien in einem Gerät.



Technische Daten

Abmessungen
33 H x 25,6 x 28 cm T

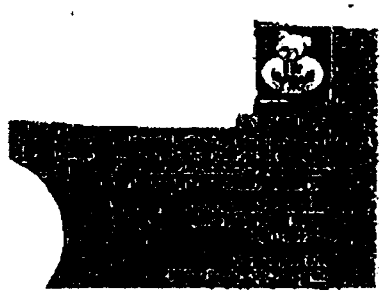
Gewicht
6,2 kg

Betriebstemperaturen
Hoch: 43 ± 3 °C
Mittel: 38 ± 3 °C
Niedrig: 32 ± 3 °C

Leckstrom
Entspricht den gesetzlichen Leckstrom-Vorschriften.

Filter
[illegible]

Gerätleistung
100-120 V~, 60 Hz, 8,5 A
220-240 V~, 50 Hz, 4,5 A
100 V~, 50/60 Hz, 9,5 A



Arizant
Healthcare

[illegible]

Temperaturmanagementgeräte

Modell 750

Temperaturmanagementgerät

- Temperaturmessung am Schlauchende
- Erhöhter Luftstrom
- Mikroprozessorsteuerung, 3 Temperaturmessungen
- Mit dem eingebauten Betriebsstundenzähler ist die empfohlene Wartung einfach zu planen.
- Über die Taste für die Temperaturanzeige kann die Dauer der Gebläseluft-Wärmetherapie verfolgt werden.
- Übertemperatur, Kalibrierung und Fehlercodebehandlung erfolgen durch einen das Bedienfeld, ohne das Gerät öffnen zu müssen.
- Kompakt und leicht

Technische Daten

Abmessungen

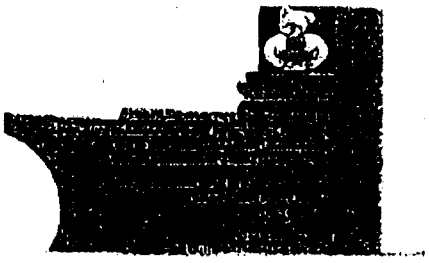
Gewicht

Betriebstemperaturen

Luftstrom

Filter

Netzspannung



Arizant

Healthcare

4. "With optimum safety and efficiency, the Bair Hugger OP blankets provide the following properties:" , if this is done in the following manner:

GROUNDS FOR THE DECISION

The action is mostly well-founded, the counterclaim is unfounded.

The plaintiff is attacking four statements made in the brochure "Blowing air is risky" and one statement on the internet page www.blowingairisrisky.com.

I. The plaintiff is entitled to injunctive relief against the defendant based on Sections 3, 5 and 4 no. 7, 8 of the German Unfair Trade Practice Act [UWG].

1. "Recent studies were frequently able to detect contamination of the Bair Hugger®1 blowers with bacteria. These devices blow many million bacteria-sized particles into the operating room every hour. It is hardly surprising that the U.S. Department of Public Health referred to the Bair Huggers as reservoir of infections."

This statement is misleading as a whole within the meaning of Sec. 5 UWG. The prohibition of misleading advertising is not only violated if the public has been deceived. Rather, it is sufficient that a statement is suitable to mislead the solicited customers and to influence them to take the wrong decisions (see Köhler/Bornkamm, UWG, 28th edition, Sec. 5 at 2.65). What is decisive is the opinion of the sections of the trade to which the advertisement is directed (Köhler/Bornkamm, ibid. at 2.67). For the accuracy of their statement, the defendants quote "Beavers, Suzanne, M.D., CDR Doug Thoroughman Ph.D. „Acinetobacter Infections among Hospitalized Patients in Kentucky - 2006" Kentucky Epidemiology Notes and Reports, 42.2: March 2007: 1-3" (pages 52-54 of the court files). But this article only generally points out that it is important to make sure that the areas that are often touched by patients and staff, such as door knobs and monitors, are cleaned.
It also says that during earlier outbreaks, fans, Bair Hugger patient warming systems, mattresses, cell phones and curtains had also turned out to be a "reservoir of infection" This statement means that the Bair Hugger - like many other devices of every day use with frequent patient and staff contact - may be a "reservoir of infection". However, in the context of the statement used by the defendants, the wrongful impression is given

to the addressed specialists (doctors, clinic administrators) that the US Department of Public Health specifically dealt with the Bair Hugger and referred to it as a problematic "reservoir of infection". The relativization that almost all frequently used and touched objects could turn out to be a "reservoir of infection" is not reflected in the statement made by the defendants, so that its statement turns out to be suitable to deceive the addressed parts of the public. These will be inclined to assume that the evaluation as "reservoir of infection" relates specifically to the "Bair Hugger", and that the "Bair Hugger" therefore bears an increased risk.

The statement is furthermore generally disparaging pursuant to Sec. 4 No. 7 UWG in the attacked specific form of presentation, because together with pictures of blood-smeared disposable gloves, bacteria in Petri dishes and enlarged photographs of dangerous bacteria, it is suitable to disparage the plaintiff's and its products' reputation with its customers. Illustrations of this kind may be customary in the medical field, but there is no objective reason to provide educational materials about the risks of bacterial contamination for the relevant parts of the public with these illustrations. Even if the defendants' statement were objectively true, its specific presentation goes beyond what is necessary for informing the customers, and is therefore generally disparaging and anticompetitive in its specific form, provided with pictures that have a negative connotation and even cause fear.

2. *"The Infection Control and Hospital Epidemiology" journal described the interior of a Bair Hugger device as a source of infection with acinetobacter which are resistant against several medicaments. Despite these reports the manufacturer does not offer a procedure with which to clean the inner side of the Bair hugger blower or hoses."*

This statement is also likely to be misunderstood in this form and therefore misleading within the meaning of Sec. 5 UWG, because according to this article, the bacteria were not just found "inside" a Bair Hugger device, e.g. the blower or hose, but in the filter, with it being unclear how long it was since the filter had been replaced before the test to which the article quoted by the defendants refers. The conclusion drawn by the defendants that the interior of the blower or the hose must necessarily be cleaned cannot be drawn based on the finding of bacteria in the filter. From the point of view of

the experts there is a qualitative difference between finding bacteria in the filter or in the blower or hose of a device. Apart from that, this statement in its specific presentation also violates Sec. 4 No. 7 UWG for the reasons already mentioned above.

3. "With particle counters it was found that more than 50 million bacteria-sized particles are blown into the operating room from the Bair Hugger devices."

The statement "it was found" is already misleading because the public will assume that it was a third party who found something out. However, footnote 3 reveals that "it was found" refers to defendant 1) or its staff itself. Of course this grammatical construction is also used to refer to oneself. But this is done only - as can be seen from Exhibit B9 submitted by the defendants (page 267 of the court files) - if one wants to express the fact that what has been said also applies to others. This is not the case here. Therefore a violation of Sec. 4 No. 7 UWG can also be established here based on the form of presentation alone.

4. "Is it possible to clean hot air hoses? NO! During routine cleaning the contaminations are not removed from the recesses of the hose. It is practically impossible to remove contaminations from the recesses in the 180 windings of a two meter hose."

In this case, too, the specific infringing embodiment is unfair based on Sec. 4 No. 7 UWG.
The question as to whether recesses in the hoses of the Bair Hugger must be cleaned because of multi-resistant bacteria, is not relevant, because in any event, the statement in connection with the pictures already mentioned is suitable to generally disparage the defendants [sic! should probably read: plaintiff] and its products.

5. „Forced-air warming units are one of the major contributors to noise pollution in the operating theatre. This noise pollution is not only irritation, it is also distracting and adds stress to the already stressful situation. The Canadian Medical Association has said, „excessive noise decreases health-care staff performance and increases patient

anxiety." The constant irritation noise of the forced-air blowers is unavoidable due to the volume of air needed to effectively warm the patient." [original also in English]

This statement is also misleading in its specific form of presentation. Here, reference is made to an article (page 59 of the court files) that relates to noise in the operating room in general. The article sets forth that noise occurs in "normal" hospital routine, e.g. by heating, air conditioning, conversations, installations on the roof, and liquids running through pipes. The article does not deal with a noise problem of Bair Hugger devices, but with noise in general. By beginning the quotation of the Canadian Medical Association with their own allegation that the Bair Hugger is one of the major contributors to noise pollution in the operating theatre, the defendants incorrectly relate the general statement of the Canadian Medical Association specifically to the Bair Hugger, and this way give rise to the impression that the conclusion about the reduced health-care staff performance and increase of patient anxiety was specifically made by the Canadian Medical Association with regard to the Bair Hugger as the cause.

II. Contrary to the defendants view, these statements also have to be assessed under the *German* Unfair Trade Practices Act. The disputed question as to whether the brochure "Blowing air is risky" was distributed in April 2009 in the Werner-Wicker Clinic - i.e. on the German market - by a sales representative of defendant 3), is not relevant, because it has meanwhile become undisputed that this brochure could also be downloaded from the internet. After the parties' submissions concerning this brochure (ROKH 7), in particular those of the plaintiff, were partly unclear and easy to misunderstand at the beginning of the proceedings, the defendants have meanwhile conceded that the brochure was available for download on the internet page www.hotdogwarming.com in the period from October 2008 to May 2009. The fact that the download was available from an English-language internet page does not exclude from the outset that the offer of the download is also intended for German customers. In the case of online advertisements, the market is the place in which the user accesses the offer as intended. The German rules of fair trading are therefore generally applicable, to the extent that the advertisement is (also) intended for German users, users access the advertisement in Germany, and commercial interests of third parties

are affected (see Köhler/Bornkamm, UWG, 28th edition, Sec. 4 at 1.208 with further references).

The English-language internet page www.hotdogwarming.com was linked to the German-language page www.dahlhausen.de . There was no special information about the Hot Dog system on the German page, but only a logo referring to the interlinked English-language page. On the English-language page it was possible to search for German dealers (page 8 of the court files) and to download German-language brochures (page 9 of the court files). A German user with an interest in the Hot Dog warming system distributed by defendant 3) - e.g. a physician or a member of the clinic administration - was therefore deliberately taken from the German page of defendant 3) to the English-language page of defendant 2) and was able to get more information about the Hot Dog system and download German-language brochures from there. In the opinion of the Court, by these means a download in Germany is specifically intended and achieved.

The internet page www.blowingairisrisky.com to be reached via the page www.hotdogwarming.com to which the German page www.dahlhausen.de makes reference is also and specifically intended for the German user. The fact that the English language of the internet page is not seen as an obstacle by the relevant public follows firstly from the fact that English is of major importance in the medical field anyway, and secondly, the defendants too, consider it sufficient for their sales efforts in Germany to merely place a reference and a link to the English-language pages of defendant 2) on the German web site of defendant 3), instead of providing more product and advertising information in German on their German-language web site.

Although the defendants allege that no single download of the brochure, or access to the English-language pages took place from Germany, this does not refute the assumption that the page was intended to be accessible from Germany. Since apart from the English-language internet pages, there was no other detailed product and advertising information about the Hot Dog warming system or its advantages over the Bair Hugger, but the Hot Dog system was undisputedly to be distributed in Germany by defendant 3), prospective customers from Germany inevitably had to obtain information from the English-language pages - assuming the accuracy of the defendants'

submission that the advertising brochures had not yet been distributed in Germany. The internet pages of defendant 2), through the link and reference on the German internet page of defendant 3), were therefore specifically intended to address the German public.

III. The statements also have to be attributed to all defendants. Defendants 1) and 2) are responsible for the statements made in the brochure "Blowing air is risky", because they undisputedly published it. Moreover, their logo and company names are on the brochure. In addition to that, defendant 2) operates the internet page www.hotdogwarming.com on which the brochure "Blowing air was risky" was kept ready for download. Defendant 3) is liable - regardless of whether it had the brochure distributed in Germany or not - because it had a link to the web page of defendant 2) on the website www.dahlhausen.de operated by it, and as a sales company, it has to accept liability for the statements made on the other internet pages - which also serve its own sales efforts.

The statement f) which could be found on the internet page www.blowinairisrisky.com is directly attributable to defendant 2) because firstly, its logo is on the web site, and secondly, the page is an advertising medium for the system of defendant 1) and 2). Defendant 1) and 3) have to accept that the statements are considered their own because of the links.

IV. The risk of a repeated commission required for a claim to injunctive relief is also present. As there is - as we have explained - an act of infringement committed by the defendants, the mere removal of links or download possibilities does not eliminate the risk of a repeated commission, because these can be restored at any time. If a violation of competition has occurred, there is a presumption of fact that the act will be repeated. Generally it is only possible to refute this presumption by the infringer submitting a cease-and-desist declaration subject to a contractual penalty (see Köhler/Bornkamm, ibid., Sec. 8 at t.34). Such a declaration has not been submitted. The presumption has not been refuted either, because defendant 1) and 2) are no longer in possession of the brochure in dispute, for example. On the one hand, the acts can be repeated on the internet at any time. On the other hand, the brochures were delivered to the sales

partner, defendant 3), for advertising the products of defendant 1) and 2). Defendant 3) is able to use these brochures for advertising purposes at any time, or defendant 1) and 2) are able to re-print the brochures edited by them and distribute them themselves.

V. On account of the anticompetitive behaviour of the defendants, the plaintiff is also entitled to damages, the establishment of which it is requesting, Sec. 9 UWG, because the defendants have at least acted with negligence. Exercising the required degree of diligence, the defendants could have and should have recognized that their statements, as presented by them in the specific composition and design of the brochure, are generally disparaging and at least liable to be misunderstood to such a degree that they give the relevant parts of the public a wrong impression. Since a damage is probable and a damages claim has therefore arisen on the merits, the plaintiff also has a right to information about the type, time or duration, and scope and intensity of the violation of competition (see Köhler/Bornkamm, ibid., Sec. 9 at 4.26).

VI. The request for publication is unfounded. The judgment can be published pursuant to Sec. 12 Para. 3 UWG if there is a justified interest in the publication. Upon balancing all interests, it has to be assessed whether the award of the right of publication is suitable and necessary in order to eliminate the continuing disturbance. Suitability has to be denied if the publication is suitable to create new confusion (see Köhler/Bornkamm, ibid., Sec. 12 at 4.7). Since the judgment concerning the statements at issue is merely limited to statements in relation to the specific infringing embodiment, a publication of the judgment could have the consequence that the public does not sufficiently understand the scope of the judgment and does specifically not limit it to the specific embodiment. Therefore a publication does not appear to be suitable to eliminate a continuing disturbance. Instead, the publication could give rise to new confusion about the correctness of the content of the statements at issue, so that this request has to be dismissed.

VII. Defendants 1) and 2) are not entitled to injunctive relief concerning the statements challenged with the counteraction. There is in particular no claim based on Sec. 5 UWG.

1. "The Bair Hugger model 505 provides safe and quiet patient warming worldwide"

a. The use of the word "safe", contrary to the opinion of defendant 1) and 2), does not give the incorrect impression that the Bair Hugger devices belonging to the plaintiff are absolutely safe and risk-free devices. The statement about the "safe" patient warming has to be interpreted in view of the specific embodiment. The information that can be found on the internet page www.arizant.com in the section "Warming Units & Accessories" in connection with the criticized statement is device-specific information, i.e. it deals with the characteristics of the device as such. The information deals with the dimensions, weight, handling and operation of the device. When it says "safe" patient warming in this context, the relevant parts of the public will only understand this statement in relation to the specific device and its technical characteristics. The public does not understand this statement to mean that the plaintiff claims its devices are generally not dangerous.

It is not inadmissible to mask out the general dangers of an infection with bacteria during operations using the Bair Hugger. Sec. 5 UWG prohibits misleading statements, but does not prohibit incomplete information. If the advertising party only deals with its own merchandise, it positive statements must be true, but it is not obliged to be complete. It does not need to provide information about circumstances which may cause concerns or prejudices against the merchandise with the buyer (see Köhler/Bornkamm, ibid., Sec. 5 at 2.113 with further references). It may be conceded to the defendants that the term "safety" can be understood as meaning technical safety, as well as in a broader sense of being safe from any kind of danger. But since the term "safety" in the present context is understood by the relevant public as technical safety, due to the context of individual product information about the device, it is admissible for the plaintiff to emphasise the technical safety of its devices and to ignore the question of safety in respect of "bacterial infections".

b) Concerning the statement that the Bair Hugger is "quiet" we again need to look at the context of the statement. For a device that works with a motor-driven blower, it does not seem to be misleading, not even from the point of view of the relevant public, if the device has a noise level of 53 dB which is comparable to the noise of a normal

conversation, to says this device is "quiet". It may be correct that this noise level may still have disturbing effects in an operating theatre. But since this is also true for "liquids flowing through the pipes" or conversations, it is obvious that this problem is due to the particular construction of the operating rooms, and not a particular noise caused by the Bair Hugger. Compared with other motor-driven devices that have a blower, such as vacuum cleaners or hair dryers, the assessment of 53 dB as quiet does at least not seem misleading.

2. "Each Bair Hugger temperature management device is tested individually in order to ensure safe operation."

Concerning the way the public understands "safety", we refer to our comments above. And it has not been demonstrated that the devices are not individually tested, as claimed.

3. "Bair Hugger OP blankets offer optimum safety."

With respect to this statement which again relates to the "safety" of the devices, we again refer to our comments above.

4. "The Bair Hugger models have a highly efficient 0.2 µm air filter."

It is undisputed that the Bair Hugger models have a 0.2 µm air filter. The question is whether the term "highly efficient" has been used correctly. The defendants as the counterplaintiffs bear the onus of presentation and proof for this. The burden of presentation and proof that an advertisement is suitable to mislead the addressed sections of the public is generally the plaintiff's. The general principles of the distribution of the burden of presentation and proof also apply here, according to which the plaintiff as the infringed party has to present and prove the facts that give rise to its claim; in contrast to that, the defendant (the infringer) has to present and prove the facts that invalidate the meaning or basis of these facts (see BGH GRUR 2004, 245 ff. no. 19 - Mondpreise?). However, defendant 1) and 2) as counterplaintiffs have merely submitted a hitherto unpublished study (Exhibit B 21) to prove their allegation that the 2 µm air filter used by the plaintiff does not meet the requirements of a "highly efficient" air filter.

Like an expert opinion furnished by a party, the submission of an unpublished study can only be considered as substantiated party submission. We also have doubts about the probative value of the MedWatch report announced as Exhibit B 44, because according to the extract from Wikipedia (Exhibit B 46) submitted by defendant 1) and 2), the job of MedWatch is merely to collect reports that relate to dangers associated with medical products, but not to perform any tests of medical products itself. There is no evidence to suggest that the MedWatch report submitted by defendant 1) and 2) is anything else but a copy of Exhibit B 21 or any other report of an unknown third party, so that this exhibit can also merely be seen as substantiated party submission. The plaintiff disputed the results of the study submitted by defendant 1) and 2) and submit values of its own according to which its air filters meet the requirements of "highly efficient" air filters. It would then have been up to defendant 1) and 2) to offer evidence of the inaccuracy of the plaintiff's allegation. However, defendant 1) and 2) failed to furnish such evidence.

VIII. As there is no right to injunctive relief, there are no claims for information, damages, or publication, either.

IX. The cost decision is based on Sec. 92, Para. 2 No. 2 ZPO [Civil Code of Procedure]. The decision regarding provisional enforceability is based on Sec. 709 sentence 1 ZPO.

Value in dispute: 150,000 €

Dr. Schwitanski Wuttke Chang-Herrmann

Executed

as Registrar of the Court

EXHIBIT E

Last Name	First Name	Company	City	State	Country	Position
Basile	Edward	King & Spalding	Washington	DC	USA	Outside Counsel
Benham	Randy	Arizant	Eden Prairie	MN	USA	General Counsel
Boese	John	Fried, Frank, Harris, Shriver & Jacobson	Washington	DC	USA	Outside Counsel
Brazil	Anthony G	Morris Polich & Purdy	Los Angeles	CA	USA	Outside Counsel
Carissimi	Vincent/Vinny	Pepper Hamilton LLP	Philadelphia	PA	USA	Outside Counsel
Cohen	Lori	Greenberg Traurig	Atlanta	GA	USA	Outside Counsel
Cronmiller	Thomas	Hisock & Barclay (now Barclay & Damon)	Rochester	NY	USA	Outside Counsel
Dobson	JD	Fleishman Hillard	Saint Louis	MO	USA	Senior Vice President
Frismanis	Brenda	3M	St. Paul	MN	USA	Assistant to Mary Cullen Yeager
Garrett	Patrick	Fleishman Hillard	Saint Louis	MO	USA	Senior Vice President
Gordon	Corey	Blackwell Burke	Minneapolis	MN	USA	Outside Counsel
Hakensen	David	Fleishman Hillard	Minneapolis / St. Paul	MN	USA	Senior Vice President
Harms	Maureen	3M	St. Paul	MN	USA	Assistant General Counsel
Hessel	Tobias	Reimann, Osterrieth, Kohler, Haft	Dusseldorf		Germany	Outside Counsel
Holden	Evan	Greenberg Traurig	Atlanta	GA	USA	Outside Counsel
Kohler / Koehler	Martin	Reimann, Osterrieth, Kohler, Haft	Dusseldorf		Germany	Outside Counsel
Kotler	Diana	Morris Polich & Purdy LLP	Los Angeles	CA	USA	Outside Counsel
Krueger	Bethany/Beth	3M	St. Paul	MN	USA	General Counsel (Visiting Litigation Counsel from Greene Espel)
Lievers	Amy	3M and Arizant	St. Paul	MN	USA	Paralegal
Losinski	Jim	Arizant	Eden Prairie	MN	USA	Paralegal
Macheel	Constance J. /Connie	3M	St. Paul	MN	USA	Assistant to Maureen Harms
Marshall	Alice	Pepper Hamilton LLP	Philadelphia	PA	USA	Outside Counsel
Masse	Mary	Arizant	Eden Prairie	MN	USA	Director of Legal Admin
McClain	Beth C	Fried, Frank, Harris, Shriver & Jacobson LLP	Washington	DC	USA	Outside Counsel
Miller-Van Oort	Sonia	Sapientia Law Group	Minneapolis	MN	USA	Outside Counsel
Monturiol	Deborah	3M	St. Paul	MN	USA	Paralegal/LTS Analyst
Ogrosky	Kirk	Arnold & Porter LLP	Washington	DC	USA	Outside Counsel
Renner	Margaret	Arnold & Porter LLP	Washington	DC	USA	Outside Counsel
Verlinghieri	Kim F.	Pepper Hamilton LLP	Philadelphia	PA	USA	Legal Secretary to Vincent V. Carissimi
Vogt	Colby	Fleishman Hillard	New York	NY	USA	Senior Vice President
Walbourn	Jason	3M	St. Paul	MN	USA	Former Senior Litigation Counsel
Walker	Steve	Fleishman Hillard	Kansas City	MO	USA	Senior Vice President
Wasson	Christopher	Pepper Hamilton LLP	Philadelphia	PA	USA	Outside Counsel
Westphal / McCullough	Jennifer	Fleishman Hillard	Kansas City	MO	USA	Senior Vice President
Yeager	Mary Cullen	3M	St. Paul	MN	USA	Associate General Counsel, Litigation Manager

EXHIBIT F

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TOMMY WALTON, Plaintiff,	)
vs.	) Civil Action No. 4:13-CV-01164
3M COMPANY; ARIZANT HEALTHCARE, INC.; AND ROBERT PRESTERA, Defendants.	)

VIDEOTAPED DEPOSITION
CONFIDENTIAL, PURSUANT TO THE PROTECTIVE ORDER

of JOHN ROCK, taken pursuant to notice to take oral deposition, at the offices of Thompson, Coe, Cousins & Irons, 408 St. Peter Street, Suite 510, St. Paul, Minnesota, on the 19th day of February, 2015, before Brandi N. Bigalke, RSA, a notary public in and for the State of Minnesota.

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products, I guess. There's projects. And my job basically entails trying to take the incredible technologies that 3M Company has at their disposal and all the smart people there and trying to connect them up with ways to help patients and prevent infections and help prevent bad things from happening to patients in the health care system.

Q. So when you're a front end innovation manager, is that within a group at 3M?

A. Yes. So we have a division called the infection prevention division, and that's the division that I work in.

Q. Okay. I'm going to try and back up and get a lot of background information. I don't want to go through it in painstaking detail but just a little bit of flavor.

Did you go to college?

A. I did, yeah.

Q. Graduate?

A. I did.

Q. From where?

A. Cretin University.

Q. Okay. First job outside of college?

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A. I worked in Glacier National Park.

Q. All right. Doing what?

A. I worked at the lodge on the east side -- I think it's St. Mary's -- and initially started out working in the gear shop there. And then they found out I had been a bank teller, and they put me in -- in the finances area.

So I -- I ran finance and then did as much hiking as I could possibly do on my off time.

Q. What's your degree in?

A. English.

Q. Any other formal education other than English degree from Cretin?

A. Oh, I've done -- I don't know if you'd call it formal or not, but I've been at countless seminars and continuing education training and patent courses and patent bar courses and things like that.

Q. And I meant more like, you know, Master's degree or --

A. No, I haven't done any Master's degrees or any of that post secondary education.

Q. Okay. When were you initially hired by Augustine Medical?

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A. January of 1990 is my hire date. I -- it seems to me I was there in December of -- of '89, but my hiring date is -- is January of '90.

Q. Tell me how you came to get that job.

A. I was working with a colleague in a design shop. We were -- and he knew Scott Augustine. He had gone to high school with Scott Augustine.

And Scott had called him up and said I need some help. I'm bringing -- I'm starting up a medical device company, and I don't -- I can't manufacture the product. And I need some help building some manufacturing equipment. And so he called him, and a short time later he called me and said come out and at least see what we're doing.

I wasn't really interested in medical devices at the time, and -- but I eventually acquiesced and went out and interviewed with Scott. And Scott offered me a job.

Q. What were you doing at the time?

A. I was a master carpenter,

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essentially running a shop that did things like built commercials and such for films and all kinds of rigging kinds of things. So special projects, things like that.

Q. When you came into Augustine Medical, what was your job title? What were you doing?

A. I -- I don't know if I even had a job title. R and D was kind of what we called ourselves.

I worked with Scott's father and a guy that he knew who had helped him build kind of a prototype -- or an initial manufacturing piece of equipment. Dave Sorvig was his name. And then my friend Randy -- I think that's all that was there at the time in the R and D lab.

And I built manufacturing equipment to make Bair Hugger blankets.

Q. What's Randy's last name?

A. Arnold.

Q. In 2002, what was your job title at Augustine Medical, if you remember? I mean, as best you can recall.

A. It was -- 2002, I'm trying to think when our general counsel left. It was either

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senior director of intellectual property or it was -- it was director of legal affairs, one of those two, depending on when Randy Benham left the company.

Q. Randy Benham was the GC?

A. He was our general counsel.

Q. After he left, you became the director of legal affairs. What -- what does that job title entail?

A. It was essentially managing the company's legal affairs.

Q. At that time after Randy left, there was no -- were no license attorneys in the company, no general counsel in other words?

A. We didn't have a general counsel position. I don't remember -- I think -- there was another attorney that worked there. She wasn't licensed to practice in Minnesota. She was probably gone by then. But I -- I don't remember the timing of when she left. She was basic -- I -- I think she was gone by then actually.

Q. When you say you were the director of legal affairs handling the legal affairs, what -- what type of legal affairs would you be

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handling?

A. Whatever legal affairs comes up in a company. So anything from employment law to intellectual property to contracts with customers, compliance matters. We were in the middle of a -- of a giant lawsuit with the Federal Government. So I was working on that case.

Q. That's the Medicare?

A. That's the Medicare fraud case, yes.

Q. When you say you were working on that, were you active in the defense of Augustine Medical?

MS. COHEN: Objection to form. And I'll just caution you if there's anything that's attorney-client privilege -- not that you're the attorney, but if you were working with any attorneys on anything that's privileged, I'm just interposing that objection.

THE WITNESS: May I have your question back, please?

BY MR. FARRAR:

Q. Yeah. Were you active in the defense of Augustine Medical?

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A. I was the liaison to the -- all -- all our outside counsel. So I worked basically as managing our outside counsel and the various matters that came up in that defense as best I could with -- with the company and -- and our outside counsel.

Q. And I understand you were the liaison, but you were doing work actively in the defense of the company; is that fair?

MS. COHEN: Objection to form.

THE WITNESS: I don't think that's fair. I'm not sure what you mean by -- by defense. So -- but our lawyers were defending us in the case.

BY MR. FARRAR:

Q. Did you have a personal opinion as to whether or not that case had merit?

MS. COHEN: Objection to form.

THE WITNESS: I think I -- it would have to be -- I -- I don't -- I don't know, you know, what my personal opinions were on that case. They evolved over time. So I -- I don't know the answer.

BY MR. FARRAR:

Q. Well, sitting here today, do you

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think that case had merit?

MS. COHEN: Objection to form. Relevance.

THE WITNESS: Yes. I think that case had merit in the end because there was a -- there were guilty pleas. There was a consultant that the company had hired that went to jail and pled guilty.

BY MR. FARRAR:

Q. Who is the consultant? What's his name?

A. Phil Zarlengo.

Q. What company did he work for, do you know?

A. I don't remember.

Q. In 2008, what was your position with Arizant?

A. Either director of legal affairs or senior director of legal affairs.

Q. What's the difference between director and senior director?

A. Experience maybe. Tenure. I don't know.

Q. When you were director of legal affairs in Arizant in let's call it the 2007/2008

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Q. In addition to working with the leading researchers and scientists, did you also reach out to independent agencies?
A. We -- we did, but -- and independent agencies on their own validated the positions that we have taken over time.
And so independent agencies such as ECRI, the regulatory bodies and -- around the world and researchers completely independent of us, I just -- comes to mind that just the recent article by Sikka who we have no relationship with published an article supporting forced-air warming and its safe and effective use just recently.
Q. Jumping to another issue, on -- on Exhibit 56 -- and you may not even need to look at it -- that was addressed in a number of questions yesterday as well as today where there's a reference to Dr. Leaper and tarnishing of his reputation.
Do you recall that?
A. I do.
Q. And I want to ask did you or to your knowledge anyone at Arizant ever tarnish Dr. Leaper's reputation?

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A. We have not and -- not to my knowledge and nor would we do that. And in fact, I think we were looking to protect his reputation in -- in that particular exhibit.
Q. I wanted to go back to some questions earlier today about your background at Arizant and your job title as director of legal affairs.
Do you recall that you were questioned about that?
A. I do.
Q. Now, when you were the director of legal affairs, did you or someone at Arizant hire outside law firms?
A. We hired numerous outside law firms, and there were numerous outside law firms already affiliated with the company when I came into the job.
Q. When it came to the actual practice of law as an attorney, was that something you did or something the outside counsel did for you?
A. Our -- our outside counsel practiced law. I was essentially the conduit and the liaison for their direction, their opinions, their advice so that we didn't have 80 people

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calling attorneys. I was essentially the touch point for our employees and the legal -- and our -- and our management team on the legal matters of the company.
Q. Did you pass on information as you said as a conduit to the outside counsel from time to time?
A. I did. Their advice and their direction and also, you know, gathered our employees and managers together to meet with counsel as well.
Q. Did you also -- in addition to sharing information with outside counsel, did you receive information from outside counsel that you then passed on to employees and people within the company?
A. Absolutely, either verbatim or by summary.
Q. Did the information flow both ways through you?
A. Counsel in and out?
Q. Yeah.
A. It absolutely did.
MS. COHEN: Those are all the questions I have at this time, Mr. Rock. Thank

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you.
THE WITNESS: You're welcome.
FURTHER EXAMINATION
BY MR. FARRAR:
Q. Mr. Rock, a few more. If you'd pull up Exhibit 45 again?
A. Yes.
Q. And you read that paragraph at the bottom of page 1 that says: Arizant has recently obtained additional evidence to support the safe use of forced-air warming including test data from Amersfoort and Aldrich?
A. Utrecht.
Q. Utrecht.
It's true that Arizant actually paid Amersfoort and Utrecht for that study, correct?
MS. COHEN: Objection to form.
THE WITNESS: I don't -- we did not -- was the question we paid them for that data?
BY MR. FARRAR:
Q. Paid for the study. You paid them for the study?
A. Paid for the study. We had -- we

EXHIBIT K

health. DEVICES

EDITORS' NOTE

Augustine Temperature Management recently published press releases, e-mail blasts, and blog entries on this article, which appeared in the April 2013 issue of ECRI Institute's *Health Devices* journal and is titled "Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice."

ECRI Institute states that it did not participate in or approve of the above-mentioned materials, and warns that they should not be construed as representing our opinion or judgment.

Our views on forced-air warming are explained in our article, and we recommend that readers go here—and nowhere else—to learn what we think.

ECRI Institute
The Discipline of Science. The Integrity of Independence.

guidance ARTICLE

FORCED-AIR WARMING AND SURGICAL SITE INFECTIONS

Our Review Finds Insufficient Evidence to Support Changes in Current Practice

Maintaining normothermia during surgery is an important measure in preventing surgical site infections (SSIs). Several technologies are available to accomplish this during surgery, including the popular method of forced-air warming (FAW). Recently, however, some member hospitals have asked us about FAW and whether it might actually contribute to SSIs. Specifically, their questions were focused on whether the use of FAW during surgery (including orthopedic implant surgery) leads to an increased rate of SSIs as compared to the use of other methods of patient warming and, if so, whether such concerns merited discontinuing the use of FAW during surgery. In response to these questions, ECRI Institute has conducted an assessment of the published literature to determine whether the evidence supports a decision not to use FAW.

Based on our assessment, we do not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. This article explains our reason for this judgment.

THE IMPORTANCE OF MAINTAINING NORMOTHERMIA DURING SURGERY

Maintaining normothermia in surgery patients has been reported to significantly lower the risk of postoperative surgical wound infections (Kurz et al. 1996, Melling et al. 2001). Hypothermia triggers vasoconstriction, ultimately resulting in a reduction of the partial pressure of oxygen in tissue. This in turn impairs the body's ability both to fight infection at the wound site and to promote wound healing. Maintenance of body temperature during and after surgery is recommended in practice guidelines by a variety of organizations, including the Centers for Disease Control and Prevention, Guideline for Prevention of Surgical Site Infection, 1999; the American Society of Anesthesiologists, Practice Guidelines for Postanesthetic Care, 2002; the American College of Cardiology/American Heart Association, ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery, 2007; and the National Collaborating Centre for Nursing and Supportive Care, The Management of Inadvertent Perioperative Hypothermia in Adults, 2008.

FORCED-AIR WARMING MAY DISTURB AIR PATTERNS IN THE OPERATING ROOM

FAW is a popular method to maintain normothermia during surgery. FAW systems (warming units and blankets) are designed to warm patients by gently blowing warm air onto the skin of the patient via an air blanket. But there are other methods to warm patients during surgery, such as conductive-fabric warmers and water-circulating warmers. The theoretical concern raised with the use of FAW is that air currents created by the system may carry microbes that might contaminate the surgical site.

Some studies have investigated this concern, looking at the impact of FAW on laminar airflow systems—especially the potential disruption of the downward airflow patterns. For example, five studies (Belani et al. 2012, Dasari et al. 2012, Legg et al. 2012, Legg and Hamer 2013, McGovern et al. 2011) demonstrate that the exhaust from FAW units results in thermal currents that rise into the downward ventilation airflow of the laminar airflow systems studied. The disruption of airflow patterns is particularly worrisome in laminar-flow and ultraclean ORs, in which a wide variety of implant surgeries are performed. The argument is that mobilization of contaminated air near the floor or decreased effectiveness of the downward laminar airflow pattern could contribute to an increased rate of SSIs, including prosthetic joint infections (PJIs), compared to when other methods of patient warming are used. This is especially concerning during orthopedic surgeries because contamination of the surgical site may present a greater risk of developing a PJI, which is

UMDNS terms. Warming Units, Patient [17-570] ■ Warming Units, Patient, Circulating-Fluid [17-648] ■ Warming Units, Patient, Conductive Layer [25-785] ■ Warming Units, Patient, Forced-Air [17-950] ■ Warming Units, Patient, Radiant [13-248] ■ Warming Units, Patient, Radiant, Adult [13-249]

harder to treat and resolve than would be the case with SSIs in general. These studies, however, only raise questions about airflow disruptions. Demonstrating that airflow patterns change when FAW is used does not establish that it results in increased bacterial contamination or increased rates of SSI and PJI as compared to use of other methods of patient warming.

WHAT THE EVIDENCE SHOWS

The literature review process we used involves articulating a specific question to answer, creating search strategies for a comprehensive and objective literature search, and identifying inclusion and exclusion criteria that are applied to each study. The studies that meet the inclusion criteria are evaluated for their design and the potential for study bias—specifically, study features that could impact whether the treatment being studied is responsible for the outcomes observed. Studies are then analyzed for the information they contain.

The question we asked was: Do surgical patients whose body temperatures were controlled with FAW systems (when used as intended) have an increased risk of SSIs compared to patients whose body temperatures were controlled by another method? Our inclusion criteria required that the study include a comparison of SSI rates and that it have at least two arms (FAW compared to at least one alternative warming technology), with a minimum of 10 patients (per arm) undergoing surgery. We also required that studies include documentation of body temperature maintenance for all methods and that they report all infections that occurred within a follow-up period of at least 30 days. (Our complete inclusion criteria and the reasoning behind them can be found in "Study Inclusion Criteria" on this page.)

Our search of the published literature identified over 180 studies potentially related to our question. These studies were all eliminated for a variety of reasons. Any study that was not clinical in nature—that is, that did not involve human surgical patients—was excluded. We also eliminated studies that looked at OR contamination when FAW units were used but did not examine SSIs. Granted, some of these studies report increased microbial contamination within FAW units (e.g., Albrecht et al. 2011) or increased particle counts (particles injected into the air, not bacteria) at monitored OR locations when FAW units were being used (Legg et al. 2012, Legg and Hamer 2013). But while studies like these raise questions, they don't establish that an increased risk of SSI exists with FAW compared to other warming technologies. For similar reasons, we excluded studies that solely examined air current patterns that may affect the distribution of microbes.

While we did not find any studies that met all our inclusion criteria, we did identify four studies that came close to meeting our criteria and that examined SSI rates following clinical procedures:

- Two studies—one by Huang et al. (2003) and one by Moretti et al. (2009)—primarily involved assessment of bacterial counts in different locations of the OR and at the surgical wound edges. These studies used slightly different approaches: Huang did cultures at the start and finish of surgery with use of an Augustine Medical Bair Hugger FAW system; Moretti did cultures with and without use of the Bair Hugger FAW system. The authors of the studies reported that no SSIs occurred in any patient in the studies (total of 46 patients combined). *Reason for exclusion:* These studies lacked a comparison of FAW to an alternative warming system.
- A study by Melling et al. (2001) looked at SSI rates in a total of 421 patients who underwent breast, varicose vein, or hernia surgeries. Patients were randomized into three groups: 138 patients with localized warming before surgery, 139 patients with whole-body FAW before surgery, and 139 patients with no warming before surgery

STUDY INCLUSION CRITERIA

The following are the inclusion criteria we used when determining which studies would be included in our analysis. These criteria were developed before the clinical literature review.

- Studies must have enrolled human subjects who underwent surgery involving the creation of a surgical wound. Studies without human subjects do not provide generalizable conclusions.
- Studies must evaluate a forced-air warming system and at least one other means of maintaining a patient's body temperature (with devices used as intended) during surgery. Such comparison studies are needed to determine the extent to which the FAW system is responsible for altering the infection risk compared to other means of maintaining a patient's body temperature, while all other factors in promoting or reducing infection risk are held constant.
- Studies must have data showing that the body temperature of the patient was maintained by both the FAW system and the comparison technology. If the comparison technology or the FAW system was not effective at maintaining body temperature, then this failure rather than other technology differences may be responsible for any differences in infection rate.
- Studies must be randomized controlled trials or nonrandomized comparison studies with at least two treatment arms.
- Studies must have at least 10 patients enrolled per study arm.
- Studies must report the number or rate of surgical site wound infections within 30 days of the surgery.
- Studies must be published in English.
- Studies must be published as full articles in a peer-reviewed journal.

guidance ARTICLE

LAWSUIT ALLEGES CONTAMINATION BY FORCED-AIR WARMER

ECRI Institute has learned that in March 2013, a lawsuit was filed against 3M Corporation alleging that a patient sustained a periprosthetic infection while undergoing hip replacement surgery as a result of contaminants being deposited in the surgical site by a 3M Bair Hugger forced-air warmer.

We have reviewed the plaintiff's petition. It does not present any new information that would alter the conclusions we have drawn in this article based on our review of the published literature.

Case information can be found in the press release from the plaintiff's attorneys at www.prweb.com/releases/2013/3/prweb10554160.htm.

(control group). This study compared the Augustine Medical Bair Hugger FAW system to the Augustine Medical Warm-Up. The Warm-Up (which is no longer available for purchase) was a noncontact normothermic wound therapy system designed to provide warmth and humidity in the wound area and was therefore not intended to maintain a patient's body temperature during surgery. The patient warming occurred for a minimum of 30 minutes before surgery. The SSI rate was not significantly different between warming systems (3.6% for Warm-Up, 5.8% for Bair Hugger, p = 0.4), but was significantly lower in warmed patients (5%) versus nonwarmed (14%, p = 0.001). *Reason for exclusion:* There was no comparison of whole-body warming methods used during surgery to maintain normothermia.

▷ A study by McGovern et al. (2011) that examined effects of warming devices on OR ventilation also provided data on PJIs in patients treated by different technologies for maintaining body temperature during surgery. The study reports on 1,437 patients who underwent joint replacement surgery; 1,066 patients had surgery during a period when the hospital used FAW, and 371 had surgery during a period when the hospital switched to using conductive fabric for warming. Data was collected retrospectively. The study reported PJI rates of 3.1% for FAW versus 0.8% for conductive-fabric warming, which was a significant difference (p = 0.024, Wald test) when data was combined for hip and knee surgeries. Based on the study's findings, the authors recommend that FAW not be used in orthopedic surgeries. *Reasons for exclusion:* This study lacked documentation of normothermia during surgery. In addition, the authors reported that both the prophylactic antibiotic regimen and thromboprophylaxis regimens were altered during the study period. Since the two types of warming treatment were not applied concurrently, other treatment differences or changes during the two different time periods may have influenced PJI rates. Other notable limitations of the study are that data was collected retrospectively rather than from a prospective study; the data was from only one hospital; and the authors did not state whether the data was collected from all patients who underwent primary hip and knee replacement surgery during the reported time periods.

Note that no information was provided on what model warming devices were used on patients in the SSI portion of the study, only whether the devices were conductive fabric or FAW. However, in the operating-theater-ventilation portion of the study, a Bair Hugger warming unit with a Model 540 FAW blanket and a Hot Dog brand Model B110 conductive-fabric blanket were used.

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

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This report appears in the April 2013 issue of ECRI Institute's monthly Health Devices journal, which is provided to members of ECRI Institute's Health Devices System, Health Devices Gold, and SELECTplus™ programs. Health Devices features comparative, brand-name evaluations of medical devices and systems based on extensive laboratory testing and clinical studies. ECRI Institute's evaluations focus on the safety, performance, efficacy, and human factors design of specific medical devices and technologies.

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EXHIBIT L

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 2

Minneapolis, Minnesota

Saturday, November 12th, 2016

Reported by:
Amy L. Larson, RPR
Job No. 115236

ALBRECHT

THE WITNESS: It depends on what you define as "cause." It was associated with.

BY MR. COREY GORDON:

Q. In your professional experience as a statistician dealing in the field of medical and biological issues, is there any difference to you between something that's associated with and something that causes?

MR. ASSAAD: Objection to form.

THE WITNESS: Yes, there is a difference between association and cause, and causation.

BY MR. COREY GORDON:

Q. And you were one of the coauthors of the McGovern study that's being characterized here. Do you agree with the characterization that your study found that forced-air warming caused a 3.8 times increase in deep joint infection rates?

MR. ASSAAD: Objection to form.

THE WITNESS: I would agree that it's associated with the 3.8 times increase, that's what the study would say.

ALBRECHT

BY MR. COREY GORDON:

Q. So you would -- you would -- you would agree, then, that you did not conclude or show that it caused a 3.8 times increase in deep joint infection rates?

MR. ASSAAD: Objection to form.

THE WITNESS: We did not prove causation.

BY MR. COREY GORDON:

Q. So -- and you would agree that this statement by Dr. Augustine is a mischaracterization of the study on which you were a coauthor?

MR. ASSAAD: Objection to form.

BY MR. COREY GORDON:

Q. Correct?

A. It's speculation, because it didn't use the exact word "causation." If I were to look for association versus causation, I'd need to have that word, if you want me to be frank with you on statistical terms.

Q. I just want you to be frank with me on whether you think that Dr. Augustine accurately characterized your study when he said, "Forced-air warming was shown to cause

ALBRECHT

a 3.8 times increase in deep joint infection rates."

MR. ASSAAD: Objection to form, asked and answered.

BY MR. COREY GORDON:

Q. Is that a correct characterization or not?

MR. ASSAAD: Same objection.

THE WITNESS: It depends on the context. It's not causation, it's association.

MR. COREY GORDON: Okay.

BY MR. COREY GORDON:

Q. I can't give you any more context on what Dr. Augustine's words are here. "Forced-air warming was shown to cause a 3.8 times increase in deep joint infection rates," is that, in your view as one of the coauthors of the study, accurate or not accurate?

MR. ASSAAD: Objection to the form, asked and answered. Object to the preamble.

MR. COREY GORDON: But you've got to move to strike it, Gabriel.

MR. ASSAAD: I'm not moving to

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strike it, I'm just objecting to it.

THE WITNESS: "More importantly, forced-air warming was shown to associate with a 3.8 times increase in deep joint infection rates," that I would agree with. With what's written there, it seems a little -- I would have to say probably not, no.

BY MR. COREY GORDON:

Q. And -- and, in fact, you recall the exercise we went through at some length in your first deposition?

A. Oh, yes.

Q. The association between forced-air warming and infection rates maybe would not be very strong if you factored out the deep vein thrombosis treatment change?

A. If you had reason to believe --

MR. ASSAAD: Objection; asked and answered.

THE WITNESS: If you had reason to believe that the standard of care was lowered for those patients in those areas, maybe. So it wasn't no thrombosis agent versus

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THE VIDEOGRAPHER: So both volumes, we're at 6:53 on record.

MS. ZIMMERMAN: Thanks.

(Whereupon, Exhibit 36 was marked for identification.)

BY MR. COREY GORDON:

Q. I'm going to show you Exhibit 36. It's an exchange of e-mails between you and Professor Nachtsheim, correct?

A. Okay. Yes, it is.

Q. Okay. And I want to direct your attention to the second page where Professor Nachtsheim says to you, "Hard to disagree with the last quote where the guys said that the data are compelling, but they don't prove the link to infections in practice and a clinical trial would be needed to do that, do you agree," question mark. Did I read that correctly?

A. I will read it just to make sure. "Interesting article. Even though they were petty hard on Scott, hard to disagree with the last quote where the guy said that the data are compelling, but they don't provide the link to infections in practice and that

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clinical trial would be needed to do that; do you agree?"

Q. You said, "Provide." I think it says, "Prove."

A. My apologies.

Q. And your response was, "Yes, I do agree with that." And, in fact, why don't you read your response.

A. Okay. "Yeah, I do agree with that. Personally, I don't think it's a good idea to use forced-air warming in implant cases sensitive to airborne contamination based off" -- "based upon its effects on clean airflow occurrence over the surgical site, but we do not have conclusive proof at this time that increased infections are the result of such ventilation disruption, nor are we likely to ever have such proof. Such a trial would involve upwards of thousands of patients and carry a $2 million price tag, at minimum cost of 2,000 a patient I'm guessing. This is one of those things where we can step close to the line, and we do have important information to present that clinicians should

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be aware of, but we also have to be careful that we do not state claims regarding proof of infection reduction. Unfortunately, Scott likes to say that he's convinced of such a relationship, even though I tell him it is unsupported and I do not agree. Well, that is the difference between research and marketing. However, he knows better than to make such statements in journal articles and does not pressure me/us to do so. As such, I figure he can do as he pleases without harm as long as he respects the research boundaries, which he has to date."

MR. COREY GORDON: Okay. Here's the deal. I have probably about two hours more of questioning for you. I know I'm bumping up to the seven-hour limit. I -- I would ask you to let me go ahead and finish up. If you want to say no, you know, absent special provisions from the court, it's a maximum of seven hours, that -- that is your privilege, and I will -- I will likely ask the -- the court to give some -- give me some additional time. They're going to have

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questions for you and, you know, I'm sure they don't want me to go on any further.

So, you know, I'm going to -- it's probably partially up to you. But even if you say, yeah, why don't you just go ahead and finish with me, they're probably going to object.

MR. ASSAAD: We --

MS. ZIMMERMAN: Should we go off the record for a minute?

MR. ASSAAD: Yeah, let's go off the record.

THE VIDEOGRAPHER: We're going off the record at 11:26 a.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: We're going back on the record at 11:31 a.m.

MR. ASSAAD: It's my understanding that the seven hours are up at this time, give or take a couple of minutes. I don't know if Mr. Gordon has any questions.

We definitely want to ask -- we definitely object to defense counsel moving